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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,947	07/14/2003	Jonathan L. Gross	AM100201 PI(WYNC-0734)	6426
38791	7590	03/22/2005	EXAMINER TUCKER, ZACHARY C	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE - 46TH FLOOR PHILADELPHIA, PA 19103			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/618,947

Applicant(s)

GROSS ET AL.

Examiner

Zachary C. Tucker

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>14Jul03</u> . | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION*****Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 21 of U.S. Patent No. 6,617,327 (Gross and Stack). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim is fully embraced in the broader claim of the issued patent. The Markush list of conditions treated by the method of claim 21 in the patent includes each condition recited in the instant claim, thus, the patented claim fully covers the subject matter embraced by the instant claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The single claim is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of obesity, vasomotor flushing and alcohol addiction, with a compound of formula I, does not reasonably provide enablement for the full scope of "eating disorders" and "sexual dysfunction," or for the treatment of cocaine addiction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claim.

Compounds according to formula I are selective serotonin reuptake inhibitors (hereinafter "SSRI"), with antagonist activity at the 5HT<sub>1A</sub> receptor subtype (paragraph bridging pages 13 and 14 of the instant specification). The therapeutic effect of the compounds of formula I arises from the SSRI effect. So, this analysis will focus on what is known about the therapeutic potential of SSRI drugs. This is the art most nearly connected with the compounds described by formula I in the claim. The specification states that the 5HT<sub>1A</sub> antagonist activity results in a faster onset of the general SSRI effect of the compounds. This has not been contested, rather certain of the disorders recited in the claim have not been found to be effectively treated with compounds having SSRI activity.

In making the determination of whether or not claimed subject matter is enabled by the disclosure, the Office relies on the following factors –

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;

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(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*In re Wands*, 858 F.2d 731, 737 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

(A) Claim 1 is drawn to treatment of obesity, eating disorders, vasomotor flushing, cocaine and alcohol addiction and sexual dysfunction, by administering to the subject a compound selected from the relatively small genus of formula I, or a salt thereof.

Two of the terms recited in the group of conditions treated by the method according to the claim are broader in scope than one might think on first inspection - "eating disorders" and "sexual dysfunction." Both of these two terms embrace different classes of conditions which are etiologically opposite one another. For this reason, the full scope of the claim is not enabled.

Specifically, anorexia nervosa and bulimia nervosa are included within the broadest reasonable interpretation of "eating disorders." Anorexia, simply put, involves eating too little food, due to a psychological aversion to it, and bulimia refers to a *cycle* of compulsive overeating followed by purging by induced vomiting or laxatives, sometimes also with excessive exercising.

Premature ejaculation (overarousal in response to sexual stimulation in males), anorgasmia (the inability to achieve orgasm, affecting both males and females), erectile dysfunction, decreased libido, vaginismus (recurrent or persistent involuntary spasm of the perineal or levator muscles that prevents vaginal penetration of any kind), combinations of these, and other conditions as well, are embraced by "sexual dysfunction."

(B) The claimed invention is a medical treatment method.

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(C) The state of the art with respect to the treatment of eating disorders, sexual dysfunctions and cocaine addiction with agents having the pharmacological activity possessed by the compound of formula I (selective serotonin reuptake inhibitors) is characterized in the following references:

Crow and Mitchell, "Rational Therapy of Eating Disorders" *Drugs*, vol. 48(3), pages 372-379 (1994).

Monteljo-Gonzales et al, "SSRI-Induced Sexual Dysfunction: Fluoxetine, Paroxetine, Sertraline, and Fluvoxamine in a Prospective, Multicenter, and Descriptive Clinical Study of 344 Patients" *J. Sex and Marital Therapy*, vol. 23(3), pages 176-194 (Fall 1997).

Gorman and Kent, "SSRIs and SNRIs: Broad Spectrum of Efficacy Beyond Major Depression" *J. Clin. Psychiatry*, vol. 60(suppl 4), pages 33-39 (1999).

Rosen et al, "Effects of SSRIs on Sexual Function: A Critical Review" *J. Clin. Psychopharmacology*, vol. 19(1), pages 67-85 (1999).

Lima et al, "Antidepressants for Cocaine Dependence." *The Cochrane Database of Systematic Reviews*, issue 2, article no. CD002950 (2003).

Crow and Mitchell state that no pharmacological agent has been shown to provide an effective treatment for anorexia nervosa, but SSRI drugs have been effective in treating bulimia nervosa (pages 376-378 especially).

Gorman and Kent teach that SSRIs are effective in the treatment of bulimia (abstract and page 37).

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The articles authored by Monteljo-Gonzales et al (page 177-179 and page 181) and Rosen et al (the whole reference) document the well-known effect of SSRI drugs to cause sexual dysfunctions.

Decreased libido, delayed orgasm or ejaculation are the most common type of sexual dysfunction that SSRIs cause.

SSRIs, however, have been suggested as, and in some cases shown to be effective treatments for premature ejaculation, however (page 187 Monteljo-Gonzales, page 70, top of column 1 in Rosen et al).

SSRIs have been extensively tested for the treatment of cocaine dependence, and have proven to be ineffective. The Lima et al flatly states that this is so (page 1, "author's conclusions").

(D) The level of ordinary skill with respect the claimed invention is that of a physician.

(E) With respect to the treatment of bulimia nervosa, decreased libido, delayed orgasm, or cocaine addiction, the art is predictable, that is, attempts to treat these conditions with a compound having SSRI activity will fail.

(F) The inventor has provided direction at pages 15 and 16 of the specification, which teaches that the compound of formula (I) can be administered in a variety of pharmaceutical compositions (tablets, capsules, elixirs, *et cetera*), and that dosages of the compound of formula (I) range from 5 to 150mg per day. No teaching as to which dosages are more preferable for which conditions is provided.

(G) No working examples of the methods claimed are reported in the specification.

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(H) Given the guidance in the disclosure, and taking into consideration what is known about the therapeutic efficacy of compounds having selective serotoning reuptake inhibition activity, a method of treating anorexia nervosa, decreased libido, delayed orgasm and cocaine addiction would not be possible with any amount of experimentation. This fact is borne out by the cited references in section "(C)" above, showing what is known about these drugs.

Applicants are, of course, invited to provide showings to the contrary.

***Allowable Subject Matter***

Claim 1 would be allowed were it amended to limit the method to treatment of obesity, bulimia nervosa, vasomotor flushing, alcohol addiction, and premature ejaculation.

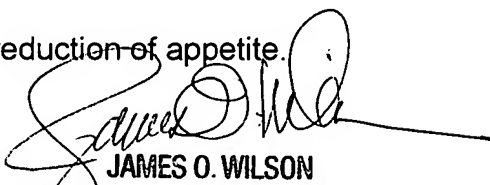
That SSRI drugs are a plausible treatment modality in alcohol addiction is demonstrated by:

Naranjo and Knoke, "The Role of Serotonin Reuptake Inhibitors in Reducing Alcohol Consumption" J. Clin. Psychiatry, vol. 62(suppl. 20), pages 18-25 (2001).

That SSRI drugs are a plausible treatment modality in vasomotor flushing is demonstrated by:

Berendsen, "The role of serotonin in hot flushes" Maturitas, vol. 36, pages 155-164 (2000).

Obesity is deemed treatable with a compound of formula (I) because of the related utility in the treatment of bulimia nervosa, where the primary mode of action of SSRI drugs in the treatment of this condition is their effect in reduction of appetite.

  
JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1800



**Comment**

Prior to preparing this Office action, the examiner contacted applicants' attorney Wendy A. Choi, to inquire whether an error had been made in the filing of this application, as all of the subject matter in the single instant claim is covered in claim 21 of US 6,617,327, to the same applicants.

Ms. Choi indicated that an Examiner's Amendment was made in the patent, wherein some of the subject matter in claim 21 thereof was to have been deleted before issuance, but the Examiner's Amendment was not reflected in the published patent, for some unknown reason. Applicants will petition for a certificate of correction in US 6,617,327.

No Certificate of Correction has been added to US 6,617,327 as of 9 March 2005. Until claim 21 in the patent is corrected, an actual case of double patenting exists between this application and the patent.

**Conclusion**

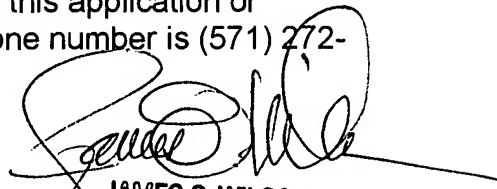
Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 6:15am to 2:45pm, Monday from 6:15am to 1:45pm and Friday from 6:15am to 3:45pm (EST). If Attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mukund Shah, can be reached at (571) 272-0674.

If, after a 24-hour period, Dr. Shah is unreachable, contact the examiner's acting supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

zt

  
JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600